

REMARKS

The Office Action mailed October 8, 2003 and reference cited therein have been reviewed. In an effort to place the claims in allowable form, Applicant has, by this amendment, canceled claims 1-4, 6-23 and 35-72 and added new claims 73-99.

The Examiner objected to claim 16 for depending on the wrong claim. Applicant agrees that claim 16 should have depended on claim 15 instead of claim 1; however, claim 16 has been canceled thereby making the objection moot.

The Examiner rejected claim 21 under 35 U.S.C. §112(1) on the basis that there is no support in the originally filed specification for the claim. As an initial matter, claim 21 is an original claim and original claims are treated as part of the originally filed specification. Irrespective of this fact, on page 9, lines 13-20, the specification states:

Yet another and/or alternative feature of this invention corresponds to the local delivery of the substance to inhibit and/or prevent restenosis, vascular narrowing and/or in-stent restenosis, such as Trepidil, through an angioplasty balloon with the physical capability to *transfer solute of the substance through the balloon membrane* to the affected sight. This delivery can be in the form of a stream, a slow oozing delivery or a bolus injection. The delivery can be made through magnetic, electrical or physical means. The delivery is accomplished through a separate lumen capable of channeling the solute of the substance to the affected area. This delivery through a balloon also delivers the substance to the sight of restenosis, vascular narrowing and/or in-stent restenosis. (emphasis added)

Applicant submits that the original specification supports the claim language set forth in original claim 21. Applicant has also amended the Specification to include the language of claim 21 in the paragraph beginning on page 16, line 8. Applicant submits that the amendment does not constitute new matter. For purposes of clarifying the questioned claim language, the slots in the

balloon are the openings in the balloon.

THE INVENTION

The present invention discloses an improved expandable intraluminal graft coated with a biological agent to inhibit PDGF activity in the passageway. After a stent is inserted into a passageway, the stent may induce some irritation in the passageway. A biological factor, such as PDGF, is turned on due to such irritation and activates the components of clotting. These components can cause clotting in the stent area or in adjacent areas. This clotting can cause the passageway to narrow or ultimately close. The biological agent coated on the expandable intraluminal graft is formulated to deactivate and/or inhibit the activity of the PDGF, thereby reducing the occurrence of in-stent restenosis, vascular narrowing and/or restenosis. The biological agent is secured to the expandable intraluminal graft by an intermediate compound. Typically the intermediate compound is designed to at least partially delay the release of the biological agent from the expandable intraluminal graft. The expandable intraluminal graft is also specially designed to have one or more smooth ends so as not to irritate a body cavity. The expandable intraluminal graft is also designed to expand in a manner that results in the longitudinal length of the expandable intraluminal graft remaining substantially constant during expansion. The combined features of the expandable intraluminal graft of the present invention is novel over the prior art and represents a significant advancement in the field of expandable intraluminal grafts.

THE SECTION 102 AND 103 REJECTIONS

Claims 1-4, 8-10, 13-15 and 18 were rejected under 35 U.S.C. §102(b) as being anticipated by Fontaine 5,443,498. Claims 1-4, 6, 7, 12-15, 18 and 22-24 were rejected under 35 U.S.C. §102(e) as being anticipated Israel 5,733,303. Claims 11, 16, 17, 19, ,20 and 35-72 were rejected under 35 U.S.C. §103(a) as being unpatentable over Israel in view of Fearnot 5,609,629.

Applicant submits that none of the references of record disclose, teach or suggest an expandable intraluminal graft for use within in a body passageway that includes 1) a body member having an intermediate compound and to secure a biological agent to the body member, and the biological agent includes Trapidil, 2) a body member design that results in the body member having substantially the same longitudinal length when the body member is in its first cross-sectional shape and in its said second cross-sectional shape, and 3) a body member having smooth ends. For at least these reasons, the claims pending in the above-identified patent application are allowable over the cited art of record.

Applicant submits that all the claims presently pending in above-identified patent application are allowable over the cited art of record, and early notice to that effect is earnestly solicited.

Respectfully submitted,
FAY, SHARPE, FAGAN, MINNICH & McKEE

By: 

BRIAN E. TURUNG
Reg. No. 35,394
1100 Superior Avenue, Seventh Floor
Cleveland, Ohio 44114-2579
Telephone: (216) 861-5582
Facsimile: (216) 241-1666